

**REMARKS*****Status of the claims***

Claims 1-44 are pending in this application. By virtue of this response, claim 1 has been amended. Support for the amendments to claim 1 may be found, for example, in paragraphs [0014], [0017], and [0044] of the specification. No new matter has been added.

Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

***Telephone interview***

Applicants would like to thank Examiner Channavajjala for extending the courtesy of a telephone interview on October 5, 2005. During the telephone interview, claim 1 was discussed. The Examiner suggested amending this claim to clarify that components (a) and (b) of the claimed kit are separate components and to add functional language with respect to the claimed compositions. By virtue of this response, claim 1 has been amended solely to incorporate the Examiner's suggested language, without acquiescence to any rejections and/or objections by the Patent Office and without prejudice or disclaimer of any previously-claimed subject matter.

During the interview, the reference from [www.wholehealthmd.com](http://www.wholehealthmd.com), which was cited in the Office Action mailed June 3, 2005, was also discussed. This reference recommends washing a bodily surface such as the hands with "warm (but not hot) soapy water" after contact with a capsaicin-containing composition, to alleviate a burning sensation. This reference was discussed in the telephone interview in the context of pending claims 25 and 34, which recite application to a bodily surface of a composition in which capsaicin has a solubility of at least about 10% w/w, and removal of this composition from the bodily surface. The Examiner asked whether capsaicin has a solubility of at least about 10% w/w in soapy water, since washing with soapy water was described

in the wholehealthmd.com website reference. Data that addresses this question is provided with this response and is discussed below.

***Solubility of capsaicin in soapy water***

Attached herewith as Exhibit A is a copy of a signed report describing experiments that were performed to determine the solubility of capsaicin in soapy water. Capsaicin was found to be insoluble (less than 0.1 % w/w) in soapy water at three different concentrations of antibacterial handsoap, even with frequent sonication over a 20 minute timeframe. These are more vigorous conditions than an individual would use when washing their hands with soapy water, as described in the wholehealthmd.com reference. An individual does not sonicate a soapy solution to remove capsaicin from his or her skin and generally does not wash his or her hands for 20 minutes. The sample with the lowest concentration of soap required overnight incubation for the capsaicin to dissolve, the sample with the second highest concentration of soap required six days to dissolve, and the sample with the highest concentration of soap did not completely dissolve even after six days of incubation. Interestingly, capsaicin was found to be less soluble as the concentration of soap was increased. The report states that according to the current USP classification (United States Pharmacopoeia, National Formulary, General Notices, page 9, USP28/NF23, January 1, 2005), capsaicin is considered to be insoluble at all three soap concentrations tested.

Thus, capsaicin does not have a solubility of at least about 10% w/w in soapy water, and the wholehealthmd.com reference does not read on the claims of this application.

### CONCLUSION

If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 524522000500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: November 9, 2005

Respectfully submitted,

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